EUROPEAN PARLIAMENT

Working Documents

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15 November 1976 DOCUMENT 421/76

Report

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposals from the Commission of the European Communities to the Council (Doc. 132/76) for

I. a directive on the approximation of the laws of Member States relating to veterinary medicinal products

II. a directive on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

Rapporteur: Mr C. NEY

English Edition

PE 46.008/fin.

By letter of 26 May 1976 the President of the Council of the European Communities requested the European Parliament to deliver an opinion on the proposals from the Commission of the European Communities for directives on the approximation of the laws of Member States relating to veterinary medicinal products and the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products.

The President of the European Parliament referred these proposals to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Economic and Monetary Affairs for its opinion.

On 23 June 1976 the Committee on the Environment, Public Health and Consumer Protection appointed Mr Ney rapporteur.

It considered these proposals at its meetings of 23 June, 28 September and 28 October 1976 and unanimously adopted the motion for a resolution and explanatory statement at the last meeting.

Present: Mr Jahn, acting chairman and vice-chairman; Mr Ney, rapporteur; Mr Ajello, Mr Didier, Mr Glinne (deputizing for Mr Walkhoff), Mr Guerlin, Sir Peter Kirk, Mr Martens, Mr Noè (deputizing for Mr Härzschel), Mr Radoux (deputizing for Mr Adams), Mr Schwabe, Mrs Squarcialupi and Mr Veronesi.

The opinion of the Committee on Economic and Monetary Affairs is attached.

C O N T E N T S

A

The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following motion for a resolution, together with explanatory statement:

MOTION FOR A RESOLUTION

embodying the opinion of the European Parliament on the proposals from the Commission of the European Communities to the Council

I. a directive on the approximation of the laws of Member States relating to veterinary medicinal products

II. a directive on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council[1]
- having been consulted by the Council pursuant to Article 100 of the EEC Treaty (Doc. 132/76)
- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Economic and Monetary Affairs (Doc. 421/76),

1. Notes with satisfaction that, with the present proposals for directives, the Commission has taken a first step towards achieving the free movement of veterinary medicinal products;
2. Welcomes the Commission's endorsement of the principle that any regulations in the field of the production and distribution of these medicinal products must have the safeguarding of public health as its main objective;
3. Regrets, however, that the Commission has opted for the introduction in stages of proposals which are too limited both in scope and content;
4. Considers that the envisaged reciprocal recognition of authorisations to place veterinary medicinal products on the market should have been treated within the framework of this directive;

[1] OJ No. C 152, 5.7.1976, p.1

5. Recommends the Commission, in view of the increasingly industrial nature of stock-breeding and in view of the fact that the number of veterinary preparations is distinctly smaller than the number used in human medicine, to broaden the field of application of the present proposals to cover medicated feedingstuffs, serums and vaccines;

6. Also regrets that, in the interests of the ultimate user, the distribution of and publicity for these medicinal products is not satisfactorily regulated;

7. Considers it desirable that supervision and inspection of the authorisations granted by the Member States should continue to be carried out in the first instance by the competent authorities of the Member States concerned;

8. Considers that it is not desirable to set up a new committee for veterinary medicinal products, since the tasks it is intended to assume can be taken over by one of the existing committees;

9. Requests the Commission to incorporate the following amendments in its proposal, pursuant to article 149, second paragraph, of the EEC Treaty.

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT

Proposals for Council Directives:

I. on the approximation of the laws of Member States relating to veterinary medicinal products

II. on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

(Submitted to the Council by the Commission on 13 May 1976)

I

Proposal for a Council Directive on the approximation of the laws of Member States relating to veterinary medicinal products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,	unchanged
Having regard to the proposal from the Commission,	unchanged
Having regard to the opinion of the European Parliament,	
Having regard to the opinion of the Economic and Social Committee,	
Whereas the primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health;	unchanged
Whereas, however, this objective must be achieved by means which will not hinder the development of industry and trade in medicinal products within the Community;	unchanged
Whereas, in so far as the Member States already have certain provisions laid down by law, regulation or administrative action governing veterinary medicinal products, such provisions differ in essential principles; whereas this results in the hindering of trade in medicinal products within the Community and thereby directly affects the establishment and functioning of the common market;	unchanged

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT
Whereas such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions;	unchanged
Whereas the provisions of this Directive which concern veterinary medicinal products are not adequate, although appropriate, for veterinary medicinal products used to confer active immunity, to diagnose the state of immunity and to confer passive immunity and for medicinal products based on radioactive isotopes; whereas it is therefore advisable not to prescribe their application to such products for the present;	Whereas the provisions of this Directive which concern veterinary medicinal products are not adequate, although appropriate, for veterinary medicinal products based on radioactive isoptopes; whereas it is therefore advisable not to prescribe their application to such products for the present;
Whereas medicated feedingstuffs do not come within the ambit of this Directive; whereas it is necessary, as much for public health as economic reasons, to prohibit the use of unauthorized medicinal products in the manufacture of medicated feedingstuffs;	deleted
Whereas marketing authorization shall be refused where a medicinal product lacks therapeutic effect or where there is insufficient proof of such effect promised by the manufacturers;	unchanged
Whereas it is advisable, in order gradually to achieve freedom of movement of veterinary medicinal products, to facilitate the granting of marketing authorization in several Member States for one and the same medicinal product;	Whereas it is advisable, in order gradually to achieve freedom of movement of veterinary medicinal products, to facilitate the granting of marketing authorizations in the Member States for one and the same medicinal product;
Whereas, for this purpose, a Committee for Veterinary Medicinal Products should be set up, composed of representatives of the Member States and of the Commission, responsible for giving an opinion as to whether a particular veterinary medicinal product complies with the requirements set out in this Directive;	Whereas, for this purpose, the Pharmaceutical Committee composed of representatives of the Member States and of the Commission, should be able to give an opinion as to whether a particular veterinary medicinal product complies with the requirements set out in this Directive;

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT
Whereas this Directive is only one stage in the achievement of the aim of freedom of movement of veterinary medicinal products; whereas, for this purpose, new measures will prove necessary, in the light of experience gained, especially within the said Committee, for the removal of the remaining barriers to freedom of movement;	Whereas, to achieve freedom of movement of veterinary medicinal products, further measures will prove necessary in the light of experience gained, especially within the said Committee;
Whereas, in order to facilitate the movement of veterinary medicinal products and to prevent the checks carried out in one Member State from being repeated in another, minimum requirements for manufacture and imports from third countries and the grant of authorization relating thereto, should be applied to veterinary medicinal products, as specified in second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products,	unchanged
HAS ADOPTED THIS DIRECTIVE:	HAS ADOPTED THIS DIRECTIVE:
CHAPTER I	CHAPTER I
Definitions and scope of application	Definitions and scope of application
Article 1	
unchanged	
Article 2	Article 2
1. The provisions of this Directive shall apply to veterinary medicinal products whether offered for sale in the form of proprietary medicinal products, ready-made veterinary medicinal products or premixes.	1. The provisions of this Directive shall apply to veterinary medicinal products whether offered for sale in the form of proprietary medicinal products, ready-made veterinary medicinal products, premixes, or medicated feedingstuffs.
2. The provisions of this Directive shall not apply to:	2. The provisions of this Directive shall not apply to:
(a) medicated feedingstuffs;	(a) veterinary medicinal products based on radioactive isotopes;
(b) veterinary medicinal products used with a view to producing active immunity, diagnosing the state of immunity and producing passive immunity;	(b) veterinary medicinal products not prepared in advance and intended for one animal.

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT
(c) veterinary medicinal products based on radioactive isotopes;	
(d) veterinary medicinal products not prepared in advance and intended for one particular animal.	
3. However, pending separate provisions for medicated feedingstuffs, a premix shall not be used for the manufacture of medicated feedingstuffs if it has not received the authorization referred to in Article 3.	3. unchanged
Articles 3 to 13 unchanged	
Article 14	Article 14
Authorization shall be valid for five years and shall be renewable for five-year periods, on application by the holder within the three months preceding the date of expiry, in accordance with the provisions of Article 13.	Authorization shall be valid for five years and shall be renewable for five-year periods, on application by the holder at least three months before the date of expiry, in accordance with the provisions of Article 13.
Article 15	Article 15
1. In order to facilitate the adoption of a common position by the Member States with regard to marketing authorizations, a Committee for Veterinary Medicinal Products, hereinafter called 'the Committee', is hereby set up; it shall be composed of representatives of the Member States and of the Commission. 2. The Committee shall, when so requested by a Member State, examine questions relating to the implementation of Articles 10, 20 and 33, in accordance with Articles 16 to 21. 3. The Committee shall draw up its own rules of procedure.	In order to facilitate the adoption of a common position by the Member States with regard to marketing authorizations, the pharmaceutical Committee, composed of representatives of the Member States and of the Commission shall, when so requested by a Member State, examine questions relating to the implementation of Articles 10, 20 and 33, in accordance with Articles 16 to 21.
Articles 16 to 18 unchanged	
Article 19	Article 19
1. If several applications have been submitted in accordance with Article 4 for marketing authorization for the same veterinary medicinal product, and one or more Member States have granted such authorization while one or more of the other Member States have refused it, one of the Member States concerned may bring the matter before the Committee.	1. unchanged

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT
The same shall apply where one or more Member States have suspended or withdrawn marketing authorization while one or more of the other Member States have not done so.	If one or more Member States have suspended or withdrawn marketing authorization the Committee shall be informed of this decision forthwith.
2. The Committee shall consider...	2. unchanged
3. The opinion of the Committee...	3. unchanged
4. The Member States concerned...	4. unchanged
Articles 20 to 32 unchanged	
Article 33	Article 33
The following particulars...	unchanged
Subsections 1 to 6 unchanged	
7. delay if any;	7. if necessary, the delay;
Subsections 8 to 11 unchanged	
The pharmaceutical form...	unchanged
The provisions of Part 1(a)	unchanged
Articles 34 to 42 unchanged	
Article 43	Article 43
1. As regards the authorization.....	1. unchanged
2. The other provisions of this Directive shall be applied progressively, within 15 years of the notification referred to in Article 42, to veterinary medicinal products placed on the market by virtue of previous provisions.	2. The other provisions of this Directive shall be applied progressively, within five years of its entry into force, to veterinary medicinal products placed on the market by virtue of previous provisions.
3. Member States shall notify the Commission, within three years following the notification of this Directive, of the number of veterinary medicinal products covered by paragraph 2, and, in each subsequent year, of the number of such products for which the marketing authorization referred to in Article 3 has not yet been issued.	3. unchanged
Article 44 unchanged	

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT

II

Proposal for a Council Directive on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

Preamble and recitals unchanged

Article 1 unchanged

Article 2	Article 2
The amendments necessary for adapting the requirements of the Annex to this Directive to technical progress shall be adopted in accordance with the procedure laid down in Article 3(5) and (6) (as amended) of the Council Directive of... relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products.	The amendments necessary for adapting the requirements of the Annex to this Directive to technical progress shall be adopted in accordance with the procedure laid down in Article 3(5) and (6) (as amended) of the Council Directive of 20 May 1975 (75/318/EEC) relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products.
The Committee referred to in Article 3 (as amended) of the said Directive may examine any question relating to the application of this Directive which is brought up by its chairman, either on his own initiative or at the request of the representative of a Member State .	The Pharmaceutical Committee set up by the Council Decision of 20 May 1975 (75/320/EEC) may examine any question relating to the application of this Directive which is brought up by its chairman, either on his own initiative or at the request of the representative of a Member State.

Articles 3 and 4 unchanged

B

EXPLANATORY STATEMENT

I. PROPOSAL FOR A COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE LAWS OF MEMBER STATES RELATING TO VETERINARY MEDICINAL PRODUCTS

A. GENERAL OBSERVATIONS

1. The present proposal for a Council directive is a first step towards approximating the laws of Member States relating to the marketing of veterinary medicinal products.

2. The aim is to apply uniform standards in granting authorizations for the production and distribution of these medicinal products. To achieve this, the Commission has opted to introduce proposals designed to implement for a number of such products the system which is already applicable to those used in human medicine. It considers that in this way the free movement of the medicinal products in question will be attained more rapidly than by means of proposals which are too broadly conceived.

3. It should be pointed out that the removal of existing barriers and the elimination of unfair competition for the production, distribution and administering of veterinary medicinal products must be accompanied by the most effective possible safeguards for public health. Your committee welcomes the endorsement of this principle as a sine qua non. The standards applied in connection with the administration of medicinal products to animals must not be allowed to fall below those applied to products used in human medicine. It notes with satisfaction, therefore, the standards laid down in Article 4, which must be complied with before authorization is granted.

4. However, it should be noted that the scope and content of this proposal for a directive are somewhat limited. The aim is that the Member States should employ the same standards, data and documents when granting authorizations for the marketing of veterinary medicinal products. Your committee regards this measure as a fundamental matter which must be settled in advance, but points out that the authorizations for marketing medicinal products remain valid only in the Member State where they were delivered. Moreover, it considered it highly desirable that the provisions of this directive should also be applicable to premixes, medicated feedingstuffs, serums and vaccines. In particular the administering of medicated feedingstuffs and the suppression of the current black market in this area calls for early Community legislation.

5. Your committee would also have liked to see the Commission go a stage further towards reciprocal recognition of authorizations granted in the different Member States. In fact it is left to the producer or to whoever is responsible for marketing the product to limit the use of these products to one or more Member States. Through common expert research and the submission of a number of uniform data and documents as laid down in Article 4, the committee belives it should be possible in the near future to achieve the free movement of existing and new and better-quality veterinary medicinal products. This cannot but contribute to the protection of public health.

6. This proposal is thus too modest and fragmentary in its approach to the problem of reciprocal recognition of authorizations for marketing veterinary medicinal products either about to be or already granted. The proposed amendments, therefore, aim at extending the field of application of the proposal for a directive and at shortening the transitional period leading up to the free movement of veterinary medicinal products. Your committee hopes that the Commission will soon draw up more extensive proposals in this field to include a procedure for granting a European authorization.

B. PROPOSED AMENDMENTS

7. Fifth recital and Article 2

As already stated in point 4, the Committee on the Environment, Public Health and Consumer Protection considers that this proposal for a directive should also be applicable - given the large quantities involved - to premizes, serums, vaccines and in particular to medicated feedingstuffs which are not aimed so much at improving the quality of animal products but rather at an accelerated and greater increase in growth, and which, if not stringently supervised, could easily be abused.

8. Sixth recital

This naturally goes out with the adoption of the preceding amendment.

9. Eighth recital

The committee wishes to emphasize that the purpose here is to give prominence to the ultimate objective of free movement with regard to the marketing of veterinary medicinal products. Replacing the words '... in several Member States' by '... in the Member States' makes this objective clearer.

10. Ninth recital and Article 15

The Committee on the Environment, Public Health and Consumer Protection considers superfluous the setting up of a new 'Committee for Veterinary Medicinal Products'. There are already in existence a Standing Veterinary Committee, a Standing Committee for Animal Feedingstuffs, a Pharmaceutical Committee and a Committee for Proprietary Medicinal Products. In view of the limited number of veterinary medicinal products and the need to safeguard public health, it is proposed that the problems raised in Articles 16 to 21 should be dealt with by the Pharmaceutical Committee. The Commission has also pronounced favourably on this.

11. Article 14

In theory, the holder of an authorization would be able to apply for a five-year renewal on the last day before the date of expiry. To prevent any possible misunderstandings and to allow sufficient time for the competent national authorities to examine applications, the proposal aims to make the wording more precise.

12. Article 43

Basing itself on the 18-month period laid down in Article 42 for the implementation of this directive, the Committee on the Environment, Public Health and Consumer Protection considers that the proposed 15-year period for applying the provisions of this directive to veterinary medicinal products that have been marketed in accordance with previous provisions should be reduced to five years. Otherwise, the free movement of the products in question would be delayed too long by this transitional directive.

II. PROPOSAL FOR A COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE LAWS OF MEMBER STATES RELATING TO ANALYTICAL, PHARMACO-TOXICOLOGICAL AND CLINICAL STANDARDS AND PROTOCOLS IN RESPECT OF THE TESTING OF VETERINARY MEDICINAL PRODUCTS

The Committee on the Environment, Public Health and Consumer Protection approves this proposal. The proposed amendments simply complete the proposed text with the Council Directive of 20 May 1975 (75/318/EEC) already approved and by mentioning the Pharmaceutical Committee, which was also set up on 20 May 1975 (75/320/EEC).

OPINION OF THE COMMITTEE ON ECONOMIC AND MONETARY AFFAIRS

Letter from the chairman of the committee to the chairman of the Committee on the Environment, Public Health and Consumer Protection

27 September 1976

At its meeting of 23 and 24 September 1976 the Committee on Economic and Monetary Affairs discussed the proposals from the Commission of the European Communities to the Council for a directive on the approximation of the laws of Member States relating to veterinary medicinal products and a directive on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (Doc. 132/76).

The first proposal in particular could considerably influence free trade in these products. Although complete freedom of movement would in principle be possible, the Commission prefers to introduce it by stages. The Commission's proposal can therefore be regarded as merely a first step towards making free trade in these products a reality.

The Commission proposes introducing, in the case of veterinary medicinal products, the system already existing for medicinal products for human use. The committee obviously agrees that for reasons of public health, authorization should be obtained for the marketing of veterinary medicinal products, since any medicinal residues in animals used for human consumption have a direct effect on human health. The Commission proposes national authorization, which means that producers of veterinary medicinal products must lodge applications in each Member State in which they wish to market them; this must be regarded as an administrative obstacle to free trade. The Committee on Economic and Monetary Affairs therefore earnestly urges the Commission to introduce a system in which marketing authorization would cover the whole Community in the new proposal it is to submit to the Council not later than four years after the entry into force of the directive, pursuant to Article 22(2) of the proposal for a directive.

Please treat this letter as the opinion for your committee on the above Commission proposals (Doc. 132/76). The opinion was unanimously adopted[1].

Yours sincerely,
on behalf of the committee,
(sgd.) K. NYBORG
Draftsman of the opinion

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[1] Present: Mr van der HEK (chairman), Lord ARDWICK, Mr ARTZINGER, Mr FABBRINI, Lord GORDON WALKER, Mr HOUGARDY, Mr NORMANTON, Mr SPRINGORUM (deputizing for Mr SCHWORER), Mr SUCK and Mr THORNLEY